PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ETOPOSIDE 100 mg/5 mL FRESENIUS

ETOPOSIDE 200 mg/10 mL FRESENIUS

ETOPOSIDE 500 mg/25 mL FRESENIUS

ETOPOSIDE 1000 mg/50 mL FRESENIUS

Concentrate for solution for infusion

Etoposide

Sugar free

Read all of this leaflet carefully before you start using ETOPOSIDE FRESENIUS 20 mg/mL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet:

1. What ETOPOSIDE FRESENIUS 20 mg/mL is and what it is used for

2. What you need to know before you use ETOPOSIDE FRESENIUS 20 mg/mL

3. How to use ETOPOSIDE FRESENIUS 20 mg/mL

4. Possible side effects

5. How to store ETOPOSIDE FRESENIUS 20 mg/mL

6. Contents of the pack and other information

1. What ETOPOSIDE FRESENIUS 20 mg/mL is and what it is used for

ETOPOSIDE FRESENIUS 20 mg/mL contains the active ingredient etoposide.

Etoposide belongs to the group of medicines called cytostatics which are used in the treatment of cancer.

ETOPOSIDE FRESENIUS 20 mg/mL is used in combination with other anti-cancer medicines in the treatment of certain types of cancers, including tumours of the testicles, the lungs or lymphatic system (non-Hodgkin's lymphoma).

Your doctor will tell you why you have been prescribed ETOPOSIDE FRESENIUS 20 mg/mL.

2. What you need to know before you are given ETOPOSIDE FRESENIUS 20 mg/mL

ETOPOSIDE FRESENIUS 20 mg/mL should not be administered to you:

- if you are hypersensitive (allergic) to etoposide or any of the other ingredients of ETOPOSIDE FRESENIUS 20 mg/mL (listed in section 6);
- if you have recently been given a live vaccine, including yellow fever vaccine;
- if you have severe liver problems;
- if you have severely impaired formation of blood cellular components;
- if you have impaired renal function;
- if you have, or have recently had chickenpox (or recent exposure to it);
- if you have herpes zoster;
- if you have bone marrow depression;
- if you are pregnant or breastfeeding or planning to breastfeed.

If any of the above affects you, or if you are unsure if they do, tell your doctor who will be able to advise you.

Warnings and precautions

ETOPOSIDE FRESENIUS 20 mg/mL should only be administered under the supervision of a medical practitioner with experience in cancer treatment. Some side effects may require immediate attention by the medical practitioner.

Talk to your doctor, pharmacist or nurse before you receive ETOPOSIDE FRESENIUS 20 mg/mL:

- if you have a bacterial infection, as it should be treated before you start treatment with ETOPOSIDE FRESENIUS 20 mg/mL;
- if you have a bone marrow disorder. Your doctor will check your blood regularly (see blood tests below);
- if you have low levels of a protein called albumin in your blood;
- if you have recently had radiotherapy or chemotherapy;
- if you have liver or kidney problems.

Allergic reaction

Some people may have a serious allergic reaction on ETOPOSIDE FRESENIUS 20 mg/mL. Tell your medical practitioner immediately if you have chills, fever, rapid heartbeat, difficulty breathing, tightening of the chest and low blood pressure. See section 4.

Blood tests

ETOPOSIDE FRESENIUS 20 mg/mL can cause a reduction in the level of some blood cells, which could cause you to suffer from infections, or may mean that your blood doesn't clot as well as it should if you cut yourself. Blood tests (white blood cells, platelets, haemoglobin) will be taken at the start of your treatment, and before each dose you take, to make sure that this isn't happening. Acute leukaemia can occur after treatment with ETOPOSIDE FRESENIUS 20 mg/mL.

If you have low serum albumin levels, you may have an increased risk for toxicities.

If you have reduced liver or kidney function, your doctor may also want you to take regular blood tests to monitor these levels.

Tumour lysis syndrome

Due to the anti-cancer treatment, cancer cells can be destroyed rapidly in large numbers. Occasionally this may cause harmful amounts of substances from these cancer cells to be released into the blood. If this happens it can cause problems with the liver, kidney, heart or blood, which may result in death if not treated. In order to prevent this, your doctor will need to do regular blood tests to monitor the level of these substances during treatment with ETOPOSIDE FRESENIUS 20 mg/mL.

Children

Safety and efficacy in children have not specifically been studied, therefore ETOPOSIDE FRESENIUS 20 mg/mL is not recommended for use in this age group.

Other medicines and ETOPOSIDE FRESENIUS 20 mg/mL

Always tell your healthcare provide if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Certain medicines may interact with ETOPOSIDE FRESENIUS 20 mg/mL. In these cases, it may be necessary to change the dose or interrupt the treatment of one of the medicines.

This is especially important if you:

- are taking warfarin (a medicine used to prevent blood clots from forming)
- are taking ciclosporin (used after transplantation)
- are taking cisplatin (a medicine used to treat cancer)
- are taking phenytoin, phenobarbital or any other medicines used to treat epilepsy
- are taking phenylbutazone, sodium salicylate, or aspirin (pain killers)

- have recently been given any live vaccines (such as yellow fever)
- are using any other medicines that inhibits bone marrow activity
- are taking any anthracyclines (a group of medicines used to treat cancer)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Pregnancy

ETOPOSIDE FRESENIUS 20 mg/mL can cause malformation of the embryo or foetus.

ETOPOSIDE FRESENIUS 20 mg/mL should not normally be administered during pregnancy unless clearly indicated by your doctor. If used during pregnancy, ask your doctor to fully inform you on the potential risk to the foetus.

Breastfeeding

Do not breastfeed if you are receiving ETOPOSIDE FRESENIUS 20 mg/mL.

Fertility

If you consider having a child after having treatment with ETOPOSIDE FRESENIUS 20 mg/mL, discuss this with your doctor or nurse.

Both male patients and female patients of child-bearing age should use an effective contraceptive method (e.g., the barrier method or condoms) during treatment and for at least 6 months after the end of treatment with ETOPOSIDE FRESENIUS 20 mg/mL.

If you are a male and are treated with ETOPOSIDE FRESENIUS 20 mg/mL, you should not father a child during treatment and for up to 6 months after treatment. If

you want a child at a later stage, you should obtain counselling on sperm preservation before starting treatment.

Driving and using machines

ETOPOSIDE FRESENIUS 20 mg/mL can make you feel tired, nauseous (sick), sleepy, dizzy or light-headed. Your vision may also be affected. If you have these side effects, you should not drive, handle tools or machines until you have spoken to your medical practitioner.

ETOPOSIDE FRESENIUS 20 mg/mL contains ethanol, benzyl alcohol and polysorbate 80

Ethanol

ETOPOSIDE FRESENIUS 20 mg/mL contains 30,5 % v/v ethanol (alcohol), which is about 1,2 g ethanol per 5 mL vial. It may be harmful to you if you suffer from alcoholism or have liver problems or epilepsy fits, if you are pregnant or breastfeeding. The amount of alcohol in ETOPOSIDE FRESENIUS 20 mg/mL may alter the effects of other medicines.

Benzyl alcohol

ETOPOSIDE FRESENIUS 20 mg/mL contains 30 mg benzyl alcohol per mL. Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children.

Tell your doctor if you have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Polysorbate 80

ETOPOSIDE FRESENIUS 20 mg/mL contains polysorbate 80.

A life-threatening syndrome, with liver and kidney failure, decline in respiratory function, fall in platelet count and swelled abdomen has been reported in premature infants when administered polysorbate 80 containing vitamin E injection.

3. How to use ETOPOSIDE FRESENIUS 20 mg/mL

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself ETOPOSIDE FRESENIUS 20 mg/mL injection. It will be given to you by a person who is qualified to do so.

ETOPOSIDE FRESENIUS 20 mg/mL is prescribed for adults only as safety in children has not been established.

The dose you receive will be individually calculated and prepared for you, depending on your type of cancer and general condition.

ETOPOSIDE FRESENIUS 20 mg/mL will be given as a slow infusion into a vein. This may take between 30 to 60 minutes.

The duration of the treatment and the number of treatments is determined by the doctor and may vary for each patient.

If you are given more ETOPOSIDE FRESENIUS 20 mg/mL than you should

Since a healthcare provider will administer ETOPOSIDE FRESENIUS 20 mg/mL, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use ETOPOSIDE FRESENIUS 20 mg/mL

Since a healthcare provider will administer ETOPOSIDE FRESENIUS 20 mg/mL, it is unlikely that the dose will be missed.

4. Possible side effects

ETOPOSIDE FRESENIUS 20 mg/mL can have side effects.

Not all side effects reported for ETOPOSIDE FRESENIUS 20 mg/mL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ETOPOSIDE FRESENIUS 20 mg/mL, please consult your healthcare provider for advice.

If any of the following happens, stop using ETOPOSIDE FRESENIUS 20 mg/mL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe allergic reactions (chills, fever, swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing).
- A potentially life-threatening skin disorder accompanied by severe skin blisters and often sores in the membranes of the mouth, nose, eyes and the anal and genital areas (Stevens-Johnson syndrome, toxic epidermal necrolysis).

These are all very serious side effects. If you have them, you may have had a serious reaction to ETOPOSIDE FRESENIUS 20 mg/mL. You may need urgent medical attention or further hospitalisation.

Tell your doctor immediately if you notice any of the following:

- Severe liver, kidney or heart damage from a condition called tumour lysis syndrome, caused by harmful amounts of substances from the cancer cells getting into the blood stream, has been seen when ETOPOSIDE FRESENIUS 20 mg/mL is taken along with other medicines used to treat cancer. Some symptoms may be nausea, vomiting, cramps, weakness, decreased urination and numbness or tingling. Your doctor will monitor your clinical condition and blood tests for signs of tumour lysis syndrome.

These are all serious side effects. You may need urgent medical attention.

Frequent side effects:

- opportunistic infections

- acute leukaemia
- bone marrow suppression (decreased production of blood cells and platelets)
- leukopenia or neutropenia (decreased production in number of white blood cells)
- thrombocytopenia (decrease in blood platelets)
- anaemia (low haemoglobin content in red cells, causing tiredness, pale skin)
- dizziness
- irregular heartbeat (dysrhythmia), or a heart attack (myocardial infarction)
- high blood pressure
- low blood pressure
- inflammation of a vein (phlebitis)
- loss of appetite
- abdominal pain
- diarrhoea
- constipation
- temporary hair loss
- darkening of skin (pigmentation)
- skin problems such as hives, itching or rash
- sore lips, mouth or throat ulcers
- nausea and vomiting
- damage to the liver (hepatotoxicity)
- increased liver enzymes
- jaundice (increased bilirubin)
- reactions at the site of infusion (pain, irritation and swelling)
- feeling weak (asthenia)

- generally feeling unwell (malaise)

Less frequent

- tingling or numbness in hands and feet (peripheral neuropathy)
- bleeding
- a sunburn-like rash that may occur on skin that has previously been exposed to radiotherapy and can be severe (radiation recall dermatitis)
- flushing
- difficulty swallowing
- a change in the way things taste
- convulsions (seizures)
- sleepiness or tiredness
- breathing problems
- pulmonary fibrosis (scarring throughout the lungs)
- interstitial pneumonitis (lung inflammation)
- bronchospasm (breathing distress caused by narrowing of the airways)
- temporary blindness
- inflammation of optic nerve
- infertility
- fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and

eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ETOPOSIDE FRESENIUS 20 mg/mL.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store ETOPOSIDE FRESENIUS 20 mg/mL

Store all medicine out of reach of children.

Store at or below 25 °C. Do not freeze. Store in the original package, in order to protect from light.

ETOPOSIDE FRESENIUS 20 mg/mL when diluted as recommended to a concentration of 0,2 to 0,4 mg/mL in a glass container, is stable for 24 hours at room temperature and exposed to ambient daylight.

Do not store the diluted product in a refrigerator (2 °C to 8 °C) as this might cause precipitation. Solutions showing any sign of precipitation should not be used.

Do not use ETOPOSIDE FRESENIUS 20 mg/mL after the expiry date which is stated on the vial and carton after EXP. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do dispose of unused medicines in drains or sewerage systems (e.g. toilets).

These measures will help protect the environment.

6. Contents of the pack and other information

What ETOPOSIDE FRESENIUS 20 mg/mL contains

The active substance is etoposide.

Each 1 mL concentrate for solution for infusion contains 20 mg of etoposide.

Each 5 mL vial contains 100 mg of etoposide.

Each 10 mL vial contains 200 mg of etoposide.

Each 25 mL vial contains 500 mg of etoposide.

Each 50 mL vial contains 1000 mg of etoposide.

The other ingredients are:

Macrogol 300, polysorbate 80 (E433), benzyl alcohol (E1519), ethanol and anhydrous citric acid (E 330)

What ETOPOSIDE FRESENIUS 20 mg/mL looks like and contents of the pack

Concentrate for solution for infusion. The product is a clear, light yellow to pale yellow solution, which is practically free from particles.

ETOPOSIDE FRESENIUS 20 mg/mL is packed in type-I, clear, moulded glass vials of 5 mL, 10 mL, 30 mL and 50 m, closed with 20 mm bromobutyl rubber closure and sealed with 20 mm flip-off Aluminium overseals (Green, Blue, Red and Yellow respectively).

Cartons contain 1 vial of 5 mL, 1 vial of 10 mL, 1 vial of 25 mL or 1 vial of 50 mL. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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ETOPOSIDE 100 mg/5 mL FRESENIUS	47/26/1174
ETOPOSIDE 200 mg/10 mL FRESENIUS	47/26/1175
ETOPOSIDE 500 mg/25 mL FRESENIUS	47/26/1176
ETOPOSIDE 1000 mg/50 mL FRESENIUS	47/26/1177

Access to the corresponding Professional Information

The professional information leaflet will be packed together with the patient information leaflet in the carton with the vial.